

# Informal Caregiving Burden in Advanced Non-small Cell Lung Cancer: The HABIT study

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**Introduction:** This study's aim was to assess economic data regarding the home assistance burden for advanced non-small cell lung cancer (NSCLC) patients in Italy.

**Patients and Methods:** One hundred four NSCLC patients in second-line chemotherapy (2LC) or in supportive therapy (ST) were enrolled in 18 Italian oncology departments and were observed for 3 months. The main caregiver's workload was assessed monthly by a task scale; other caregivers' activities were also registered. Eastern Cooperative Oncology Group performance status was assessed by physicians, and patients completed the Lung Cancer Symptoms (LCS) subscale. Formal caregiving time was valued according to market prices; informal caregiving hours were valued using the wage rate for an equivalent service. Covariance analysis was performed to check for influential factors in assistance costs.

**Results:** The mean age of the total sample was 65.5 years, and prevalence of males was over 80%. In over 70% of cases, the principal caregiver was patient's spouse, living with the patient and not working. Principal caregiver support was the main cost item: €2,368 in 2LC and €2,805 in ST, representing 74% of total tri-monthly assistance costs. Regression analysis showed a positive

correlation between the severity of symptoms and the costs of assistance.

The caregiving burden was higher in patients with bone and/or cerebral metastases; other metastasis sites seemed to have no impact on assistance costs.

**Conclusion:** Considering quality of life as the ultimate health outcome, clinicians are challenged to contribute to a research and policy agenda that holds burden of care in due consideration.

**Key Words:** NSCLC, Informal caregiving, Assistance burden.

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Lung cancer is the leading cause of cancer-related mortality in both men and women because lung carcinomas are frequently diagnosed at an advanced stage, conferring a poor prognosis. The incidence of lung cancer in Italy in 2002 was about 37,000 new cases (65/100,000 inhabitants), and it is forecasted to increase in the coming years (71/100,000 inhabitants in 2010) because of the aging population.<sup>1</sup> Non-small cell lung cancer (NSCLC) represents roughly 80% of all lung cancer cases.<sup>2</sup>

Many studies assessed health care costs consequent to this disease,<sup>3–6</sup> and all report considerable resource consumption and, consequently, significant financial spending. A cost-of-illness study conducted in Italy, observing 189 patients with advanced NSCLC for 6 months or until death, reports a very high burden to the National Health System for patients treated with first- and second-line (2LC) chemotherapy, and also for patients receiving best supportive care.<sup>7</sup> Patients in best supportive care were found to require the highest monthly per-patient hospitalization costs (equal to €2298), whereas patients in 2LC generated the greatest chemotherapy-related adverse-event costs (up to €269 per month).

Cancer care is increasingly transferred from the inpatient to the outpatient setting,<sup>8</sup> and the burden of caring for cancer patients, especially elderly subjects, is falling increasingly on their families, with a continuous growth of informal assistance costs.<sup>9</sup> Few studies have examined this issue, highlighting that informal caregiving accounts for a substantial proportion of nonmedical costs incurred by cancer patients.<sup>10–12</sup>

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Time and difficulties encountered in performing caregiving tasks were evaluated among 78 family caregivers of patients with lung cancer.<sup>13</sup> The most time-consuming tasks for adults, children, and spouses were emotional support, transportation, and monitoring symptoms. The most difficult duties were emotional support, behavioral management, monitoring symptoms, and household tasks. Family caregiving is, therefore, a resource-consuming activity necessitated by cancer, and it should not be forgotten when assessing the direct costs of cancer.

The HABIT study (Home Assistance Burden in Lung Tumor) is a longitudinal, prospective, multicenter, national study aimed at assessing the costs of informal care in advanced NSCLC patients in Italy—either those treated with chemotherapy or those receiving supportive therapy (ST)—completing the information available on the direct medical costs of this disease and providing an estimation of the costs that the families or social security would have to support if the informal assistance could not be provided by family members.

## PATIENTS AND METHODS

Study data were collected in 18 oncology centers all over Italy. Centers enrolled consecutive patients treated with 2LC or ST, referring for control visits, and observed them for 3 months or until death; patients' treatment changes were possible during the study period, but without affecting the initial assignment of such patients to the relevant group on enrollment. A detailed study flow chart is shown in Figure 1. Considering that supportive care patients can avoid controls at the center and receive only home care or be institutionalized in hospices, control of enrollment was centralized, with the aim of stimulating enrollment of supportive care subjects, if necessary, to prevent this treatment group from being too scarce and thus affecting the cost calculation. Exclusion criteria were concomitant participation in clinical studies, the absence of a regular caregiver, and the likelihood of an unfavorable prognosis in the next 3 months. The study protocol was approved by the ethics committees of all participating centers, and patients were asked to provide their written consent to personal data treatment before the start of data collection. Demographic and anamnestic data were reported by physicians on a paper case report form; performance status has been assessed monthly through the Eastern Cooperative Oncology Group (ECOG) performance scale.<sup>14</sup> Informal caregiving time was assessed through a task scale derived from Montgomery et al.<sup>15</sup>

The scale consisted of seven types of tasks (bathing and dressing, feeding, housework, moving inside the house, transportation, nursing, administrative tasks), and the caregivers were instructed to assess how many hours per week they spent performing each task. Furthermore, each main caregiver gave information about the presence of secondary supporting caregivers and of paid, specialized, or generic caregivers (e.g., nurse, physiotherapist, or housemaid). At baseline and at each monthly interview, each patient completed the Lung Cancer Symptoms (LCS) subscale of the FACT-L questionnaire,<sup>16–18</sup> which is available in Italian and is suitable for assessing symptoms in advanced NSCLC patients.

Data were inputted into an MS SQL server database through a Web application, which was made available only to authorized users and consisted of html pages with online control functions of the inputted information.

## Statistical Analysis

The numbers of monthly and trimonthly hours of paid and informal caregiving (principal plus additional family caregivers) were calculated. To allow for 8 hours of sleep/personal care, a limit of 16 hours per day (112 per week) was imposed for any caregiver.

In the longitudinal analysis, patients were maintained in their respective initial assignment groups, and we analyzed the modifications of variables concerning patients' clinical status and assistance needs, from baseline to the end of observation period, in the two treatment groups.

Regarding patients' clinical situations (ECOG and LCS subscale of the FACT-L questionnaire), data were analyzed according to literature-based methods or to the scale manuals prepared by the authors of the questionnaires. The longitudinal analysis within groups described the scale scores at single visits and the variations in disease-specific symptoms, and each patient's performance status change between the baseline visit and the last assessment. Missing items of the LCS FACT-L scale were replaced (but only if at least four items were answered) by using the following formula: "Sum of items score  $\times$  7/number of answered items." Patients with a score variation of 2 or more were considered improved, whereas a score variation of less than 2 meant aggravation of the patient's condition.<sup>19</sup>

## Cost Analysis

For each identified category, literature-based unit costs were set on resources, expressed in physical units (hours of assistance). For fee-based assistance, the relevant national

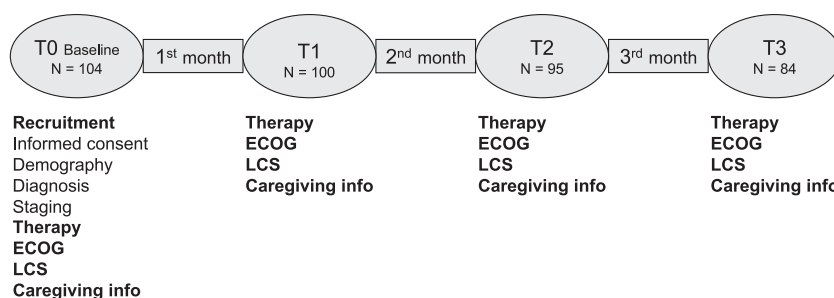


FIGURE 1. Study flow chart.

**TABLE 1.** Unit Costs and Relevant Sources

	€/hour	Reference
Nurse	34.8	National Federation of Colleges of Nursing (www.ipasvi.it)
Physiotherapist	20.66	Ministerial Decree of July 22, 1996. Outpatient National Tariffs, Official Gazette n. 216, November 14, 1996
Housekeeper	4.33	National Housekeepers Contract. CCNL 8.3.2001, art 34

tariff was applied to each service. Regarding informal care, a replacement cost was applied, assessing values to physical units on the basis of hourly costs of the closest professionals to the assistance activities performed by caregivers—nurse, for health care-type services; home help, for housework—referring to the relevant national collective agreement. Unit costs and the relevant sources are reported in Table 1.

### Identification of Cost Determinants

Factors, increasing the assistance need and respective costs, were identified by means of several covariance analyses, using the following variables as covariate values: patient's age, type of therapy, cancer stage, time elapsed from first diagnosis, caregiver's living situation (with the patient or not), ECOG scores, and LCS scores. For patient's age, type of therapy, and caregiver's home situation, the correlation between costs and initial value was analyzed. For the LCS subscale of the FACT-L questionnaire, and for the ECOG scale, the correlations of costs with initial score and costs with score difference between first and last assessment were analyzed.

A multiple-regression model was applied to evaluate which of the variables described above significantly predicts the assistance costs; these were converted into logarithms to normalize the data.

An additional analysis was conducted to investigate the relation between the presence and localization of metastasis and the cost of the informal care provided by the principal caregiver. Sample was stratified according to metastasis presence and type, regardless of the therapy, and assistance costs were compared between groups, also excluding costs related to domestic activities, which might be performed by the caregiver independently of the presence of a cancer patient.

### RESULTS

From February to June 2004, 104 dyads consisting of patients with advanced NSCLC and their family caregivers were enrolled in 18 oncology centers. No significant differences were found in the demographic variables in the two groups, 2LC and ST, as shown in Table 2. Our sample had a mean age of >60 years, with a wide range of 35 to 82 years; the prevalence of males was more than 80% in both groups. The large majority of subjects were not on paid job at the time of enrollment, and only five subjects declared that they had ceased working because of the disease before the study's start, whereas the others retired for reasons different from the disease under consideration. Eighty-two percent of patients

**TABLE 2.** Patient Characteristics

	2LC	ST	Total
No. of patients	55	49	104
Percent male	82	90	86
Age (yr)	62.8 (9.4)	68.5 (9.3)	65.5 (9.8)
Working situation (%)			
Working	13	6	10
Not working	87	94	90
Stage (%)			
IIIb	18	18	18
IV	82	82	82
Months since first diagnosis	17.1 (14.3)	27.5 (46.1)	22.0 (33.5)
Previous surgery: yes/no (%)	33/67	31/69	32/68
Metastasis (%)			
Bone or cerebral	40	54	47
Other	42	25	34
Absent	18	21	19

2LC, second-line chemotherapy; ST, supportive therapy.

**TABLE 3.** Principal Caregiver Characteristics

	2LC	ST	Total
Percent female	72	76	74
Age (yr)	53.1 (14.6)	56.7 (14.0)	54.7 (14.4)
Living situation (%)			
With the patient	91	77	84
Without the patient	9	22	15
Missing	—	2	1
Degree of relationship with patient (%)			
Spouse	76	65	70
Son/daughter	15	21	18
Other	9	14	12
Working situation (%)			
Working	28	26	27
Not working	72	74	73

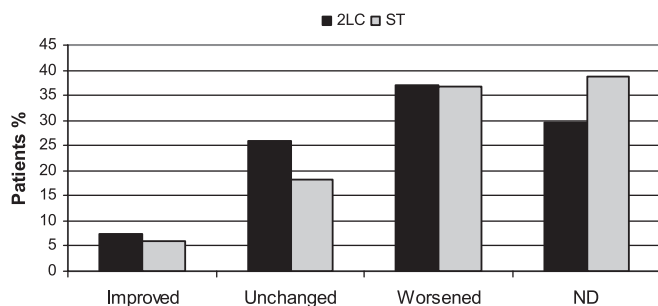
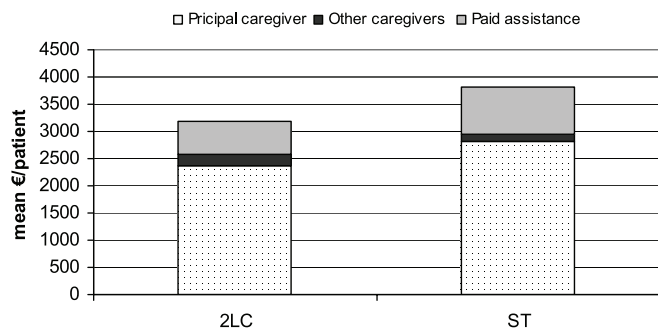
had stage IV NSCLC with prevalent bony and cerebral metastases, especially in ST patients. During the study period, 53% of patients in 2LC changed therapy, whereas only 6% of ST patients switched to chemotherapy. Generally, the main caregiver was the patient's spouse, usually the wife, living with the patient and not working in over 70% of cases. Only one ST patient changed caregivers during the study period (Table 3).

Patients' performance statuses declined in both groups throughout the study. During the 3 months of observation, 12 patients died in both groups: 22% of initial 2LC cases and 24.5% of initial ST cases. Table 4 shows the deterioration of performance status in both patient groups; at baseline, the majority of patients were asymptomatic or fully ambulatory regardless of the treatment, whereas after 3 months, 5 and 12% of patients in 2LC and ST, respectively, were bedridden. Also, the seriousness of symptoms worsened during the study period. Figure 2 shows the percentages of patients with

**TABLE 4.** Eastern Cooperative Oncology Group Performance Status at Baseline and Last Observation: Percentage of Patients in the Different Scores

Scores	Baseline (%)		Last Observation (%)	
	2LC	ST	2LC	ST
0-1	75	69	42	47
2-3	25	27	31	16
4	—	4	5	12
5	—	—	22	25

2LC, second-line chemotherapy; ST, supportive therapy. Score key: 0, asymptomatic; 1, symptomatic but fully ambulatory; 2, symptomatic and in bed less than 50% of the day; 3, symptomatic and in bed more than 50% of the day; 4, bedridden; 5, dead.

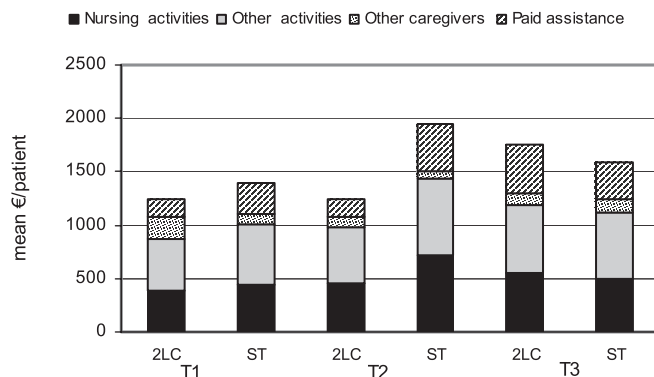
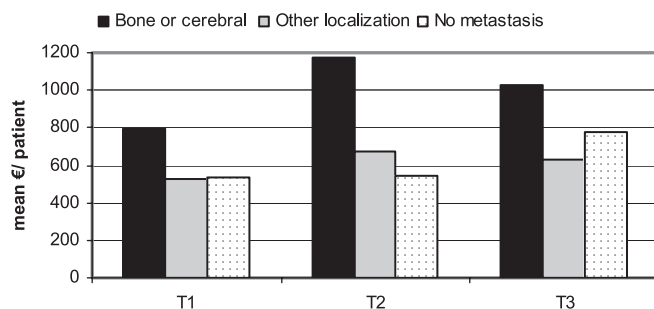
**FIGURE 2.** Lung Cancer Symptoms subscale. Symptoms changes between baseline (T0) and last observation (T3).**FIGURE 3.** Average trimonthly costs per patients in the two treatment groups.

improved, worsened, or unvaried conditions at last interview in comparison with the baseline, in the two treatment groups.

Similar percentages of patients (37% in both groups) worsened or improved (7% in 2LC and 6% in ST) after 3 months; the high percentage of missing assessments is largely attributable to patient deaths.

One hundred one patients were eligible for the informal caregiving burden. Two patients were excluded from the cost analysis because of insufficient information, and one was excluded because he was assisted by a professional caregiver for about 145 hours per week, representing the unique case of this type of assistance in our sample.

The informal care given by the main caregiver was the main assistance cost item (Figure 3), €2.368 2LC and €2.805 ST, representing 74% of total assistance costs in both groups

**FIGURE 4.** Monthly assistance costs per caregiver type. The nursing component of principal caregiver activities is presented separately from the other tasks.**FIGURE 5.** Monthly informal assistance cost (principal caregiver tasks, excluding housekeeping) per metastasis presence and localization.

during the study period. The analysis of monthly assistance costs showed constant increases, except for the cost at the third month of observation, in the supportive care patients' group (Figure 4).

The regression analysis, performed to identify the determinants of costs, did not show statistically significant correlations between the three monthly costs and the variables considered in our model, except for caregiver's living situation and score variations on the LCS subscale. Assistance costs were higher when caregivers did not live with patients ( $p < 0.0001$ ), and score variations on the LCS subscale were in inverse relation to the assistance costs; that is, score decreases correspond to cost increases ( $p < 0.0001$ ). LCS score decreases correspond to worsened symptoms perceived by patients; this correlation associates a patient's aggravation with an increased need for assistance and, consequently, with higher costs.

Figure 5 shows assistance costs for the whole sample, stratified by presence and type of metastasis, regardless of the type of treatment administered to patients. Cerebral and/or bony metastases caused, on each monthly check, significantly higher assistance costs to the main caregivers ( $p < 0.0001$ ).

## DISCUSSION

The results of the HABIT study show that advanced NSCLC patients require extensive assistance from family



caregivers. Caregiving burden was associated with household tasks, supporting patients in daily living activities, nursing care, managing transportation, and illness-related finances.

The nature of informal caregiving activities influenced the costs in our study, because the time devoted to the different tasks was valued according to a replacement cost method, which estimates what the financial burden would be if the same activities were performed by paid professionals. According to this perspective, some tasks are time consuming as household activities but have a lower market value than others, such as nursing ones, which are less time intensive.

Assistance costs tend to increase with time in both chemotherapy and supportive care patients. Performance status variation measured through the ECOG scale did not show any influence on assistance costs, whereas the regression analysis showed a correlation between increases in symptom severity as perceived by patients (LCS scores) and the increases in assistance costs. It should be noted that our sample comprised patients enrolled at oncology centers who were still able to go to the hospitals for routine visits; terminally ill or fully bedridden patients could not be represented in this sample, because their condition prevented them from referring to the centers, as reflected by the low percentage of patients with ECOG scores of 4 (bedridden) at any assessment time.

The LCS subscale is not only a validated patient instrument with reliability in detecting clinically significant changes in NSCLC-related symptoms; it is also a good predictor of assistance need and costs, and it may have a role in clinical practice. Observed changes in patient-reported outcomes may facilitate patient–physician communication, especially in patients with declining outcomes, and it has been shown that effective patient–physician communication is associated with lower patient distress and improved physical outcomes.<sup>20</sup> Our experience suggests that the LCS subscale may provide additional information about a patient's status and need for assistance that is not provided by traditional clinical parameters of function; this information could be useful to clinicians to enlighten caregivers as to the future burden of the disease.

It should be noted that our sample was representative of the patients referring to oncology centers for regular visits therefore patients that despite we introduced very few enrollment criteria.

Caregiving costs were higher when the main caregivers did not live with the patients; this is probably because spouse caregivers, mostly women in our sample, are more likely to attend normally to the needs of their spouses,<sup>21</sup> and they might not consider caregiving to be solely related to the disease as nonspouse caregivers would.

Caregiving burdens were constantly higher at all observation times in patients with bony and/or cerebral metastases; other metastasis localizations seemed to have no impact on assistance costs.

Our model was able to explain about one third of the assistance cost variability, showing that there is room for improvement in the detection of caregiver burden components. A limitation of our task scale is that we did not include

emotional support among the task categories, even though previous studies<sup>13,22</sup> have shown that this was the most time-consuming task. Our choice was based on our objective of estimating a possible replacement cost for informal care, and we believe that emotional support is a caring activity that a family could not successfully delegate to a professional caregiver being paid for his or her time.

The increasing responsibilities of families to provide care in the face of limited external support, and the consequences of that caregiving for patients and families, are raising serious concerns among clinicians. Considering quality of life as the ultimate health outcome, clinicians are challenged to contribute to a research and policy agenda that holds the burden of care in due consideration. It has been shown that the severity of symptoms triggers the assistance cost; therefore, in evaluating new and more effective cancer therapies to preserve quality of life, it is also worth assessing the impact of home assistance, whether it is provided by family members or by paid professionals.

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